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| TO ANICHITTAL   |                                      | Applic               | ation Number                           | 10/600,80  | 05   |  |
| TRANSMITTAL FORM  (to be used for all correspondence after initial filing)  |                                      | Filing Date          |  | June 19, 2003  |  |  |
|   |                                      | First Named Inventor |  | SACHS, M.D., DAVID P.L.                                    |  |  |
|   |                                      | Art Unit             |  | Unassigned   |  |  |
|   |                                      | Exami                | ner Name                               | Unassigned   |  |  |
| Total Number of Pages in This Submission  |                                      | Attorn               | ey Docket Number                       | 013012-0   | 000220US   |  |
|   | ENCI                                 | OSURE                | S (Check all that appl                 | y)   |  |  |
| Fee Transmittal Form  | ☐ Drawing                            | g(s)                 |  | After A  | Illowance Communication to Group                     |  |
| Fee Attached  | Licensi                              | ng-relate            | d Papers                               | Appeal Communication to Board of Appeals and Interferences |  |  |
| Amendment/Reply   | Petition                             |                      |  |  | l Communication to Group (Appeal Brief, Reply Brief) |  |
| After Final   |                                      | to Conv<br>onal App  |  | Proprie  | etary Information                                    |  |
| ☐ Affidavits/declaration(s)   |                                      |                      | ey, Revocation espondence Address      | Status   | Letter   |  |
| Extension of Time Request   |                                      |                      | al Disclaimer                          |  | Other Enclosure(s) (please identify below):          |  |
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| Certified Copy of Priority Document(s) Remai  |                                      | ks                   | The Commissioner is a Account 20-1430. | authorized to  | charge any additional fees to Deposit                |  |
| Response to Missing Parts/ Incomplete Application   |                                      |                      | J                                      |  |  |  |
| Response to Missing Parts under 37 CFR 1.52 or 1.53   |                                      |                      |  |  |  |  |
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| Firm Townsend and Tov   |                                      |                      |  |  |  |  |
| or Individual James M. Heslin Reg. No. 29,541   |                                      |                      |  |  |  |  |
| Signature   | Signature                            |                      |  |  |  |  |
| Date 7/29/03  |                                      |                      |  |  |  |  |
| CERTIFICATE OF TRANSMISSION/MAILING   |                                      |                      |  |  |  |  |
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| Typed or printed name Edward Masir  | Typed or printed name Edward Masinas |                      |  |  |  |  |
| Signature   | M                                    | asmar                | Date                                   | 07-30-03   |  |  |

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Attorney Docket No.: 013012-000220US

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on 07-30-03

TOWNSEND and TOWNSEND and CREW LLP

By: Zdward Masmas

**Edward Masinas** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

1

DAVID P.L. SACHS, M.D.

Application No.: 10/600,805

Filed: June 19, 2003

For: METHODS FOR NICOTINE

REPLACEMENT DOSAGE

**DETERMINATION** 

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

**§1.98** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 08/422,381, filed April 13, 1995 (Attorney Docket No. 013012-000210). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

DAVID P.L. SACHS, M.D. Application No.: 10/600,805

Page 2

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that <u>no fee is required</u> for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

James M. Heslin Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8<sup>th</sup> Floor
San Francisco, California 94111-3834

Tel: 650-326-2400 Fax: 650-326-2422

JMH:bjl 60005706 v1

Pages, Columns, Lines, Where

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**U.S. PATENT DOCUMENTS** 

**Publication Date** 

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07-24-1990

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No.1

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

**Document Number** 

US-4,943,435

Number Kind Code<sup>2</sup> (if known)

Page of

| Complete if Known             |                         |  |  |  |
|-------------------------------|-------------------------|--|--|--|
| Application Number 10/600,805 |                         |  |  |  |
| Filing Date June 19, 2003     |                         |  |  |  |
| First Named Inventor          | SACHS, M.D., DAVID P.L. |  |  |  |
| Art Unit                      | Unassigned              |  |  |  |
| Examiner Name                 | Unassigned              |  |  |  |
| Attorney Docket Number        | 013012-000220US         |  |  |  |

Name of Patentee or

Applicant of Cited Document

Baker et al.

|                     | AB           | US-5,069,904  |  | 12-03-199                             | 1                              | Masterson                      |  |  |   |                |
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| Examiner Cite No.1  | Cite         | Foreign Patent Document   |  | Dublication Date                      | Name of Patentee or            |                                | Pages, Columns, Lines,<br>Where Relevant |  | } |                |
|                     |              | Country Code <sup>3</sup>   | Number⁴  | Kind Code <sup>5</sup> (if known)     | Publication Date<br>MM-DD-YYYY | Applicant of Cited<br>Document |  | Passages or Relevant<br>Figures Appear |   | T <sup>6</sup> |
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| Examiner Initials * | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  |                                       |                                |                                | ٦  | Γ <sup>2</sup>                         |   |                |
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|                     | AG           | Kochak et al., "Pharmacokenetic Disposition of Multiple-Dose Transdermal Nicotine in Healthy Adult Smokers"   |  |                                       |                                |                                |  |  |   |                |

| Examiner  | Date       | · |
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of Smoking Cessation Therapy" Meth. and Find. Exp. Clin. Pharmacol. (1989) 11(3):219-222.

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Pharmaceutical Research (1992) 9(11):1451-1455.

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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| Applicati n Number     | 10/600,805              |  |  |  |  |
| Filing Date            | June 19, 2003           |  |  |  |  |
| First Named Inventor   | SACHS, M.D., DAVID P.L. |  |  |  |  |
| Art Unit               | Unassigned              |  |  |  |  |
| Examiner Name          | Unassigned              |  |  |  |  |
| Attorney Docket Number | 013012-000220US         |  |  |  |  |

| FOREIGN PATENT DOCUMENTS |              |  |                                |   |  |    |  |
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| Examiner<br>Initials*    | Cite<br>No.1 | Foreign Patent Document  Number <sup>4</sup> Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>6</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T⁰ |  |
|                          | AI           | Ross et al., "Pharmacokinetics of Multiple Daily Tr<br>Research (1991) 8(3):385-388.   | ransdermal Doses of            | Nicotine in Health Smokers                            | " Pharmaceutical   |    |  |
|                          | AJ           | Sachs et al., "Effectiveness of a 16-Hour Transder<br>Group Counseling" Arch. Intern. Med. (1993) 153:                       |                                | n a Medical Practice Setting                          | Without Intensive  |    |  |
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